

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION**

IN RE ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	X : : : : : X	CIVIL ACTION NO. 2:12-md-02327 <u>MDL No. 2327</u> Judge Joseph R. Goodwin
This Document Applies To All Actions	: :	

DECLARATION OF KATE GRAYSON

I, Kate Grayson, hereby declare as follows:

1. I am the President and Chief Executive Officer of Steelgate, Inc. ("Steelgate"), a company in Bradenton, Florida, specializing in biomedical specimen (tissue and device) retrieval and storage.
2. Steelgate currently stores numerous transvaginal mesh and pelvic floor tissue excised or explanted from Plaintiffs, including, but not limited to, slides, special stains, blocks, and gross material ("Explants"). I oversee the staff responsible for retrieving such Explants. Steelgate is frequently asked to assist counsel in obtaining Explants prior to a planned surgery; however, many requests are often submitted to Steelgate post-operatively. In order to accomplish this, my staff works directly with hundreds of hospitals throughout the United States and I am familiar with the policies of such hospitals, as it relates to the handling of requests to preserve Explants.
3. Steelgate has been asked to retrieve, store, track, photograph and provide all of the services of a biorepository in this Transvaginal Mesh (TVM) litigation over the last few years. We have worked closely with plaintiffs' counsel, defense counsel, experts, hospitals, pathology departments and risk management offices across the United States in order to properly collect, preserve and distribute mesh explant samples, paraffin blocks and pathology slides in this litigation. We have been asked to do this for literally thousands of mesh pathology specimens.
4. As a result of my company's core practice and expertise, as well as our past and ongoing experience in the preservation of mesh pathology in the TVM litigation, I have observed and had to deal with numerous challenges, concerns, problems, and complexities with regard to proper protocols for handling the enormous issue of mesh pathology preservation and, as much as any party, would like to see proper protocols and operating procedures be put in place in order to preserve these extremely significant pieces of evidence in the most efficient, cost-effective and accurate manner.

5. I have reviewed Ethicon's Motion for Order Requiring Preservation of Explanted Mesh, Plaintiffs' Response to Ethicon's Motion, Ethicon's Reply to Plaintiffs' Response as well as all of the attached exhibits.
6. I have been asked for my professional opinion as an expert in the retrieval and storage of biomedical specimens regarding the above-referenced documents and hereby provide such opinions and hopefully, to also provide some meaningful suggestions in how to move forward on the most appropriate and practical preservation order possible.
7. My review of Ethicon's Motion and their Reply, including the attachments to these documents, reveals a critical problem. In the Conclusion of their Motion and in their Reply, Ethicon indicates that Plaintiffs should not only advise their healthcare providers of the duty to preserve the explanted mesh specimens, but also of "the appropriate measures for doing so." In their Reply, Ethicon states that this has already been done in another case and attaches a letter to a hospital pathology department with a set of instructions, which the parties demand that the pathology department follow. Herein lies what has become a tremendous problem for our company, for pathology departments around the country and for the various parties to these mesh litigations.
8. Most hospitals are already overburdened with the handling of routine patient care and corresponding analytical services, such that even the simple request for preservation of pathology material, contemplated by Ethicon in Exhibit A to its Reply document, adds an additional layer of resource challenges for a task that is also of lower priority to these departments.
9. Two requesting parties may contribute to errors in how pathology material is shipped and to whom. A hospital is not sensitized to the difference in the requesting parties and has shipped the wrong specimen to unintended recipients on a number of occasions. It should be understood that when hospitals are receiving these types of requests, they see them as overly complex, not in keeping with their standard operating procedures, often get Risk Management or in-house attorneys involved, and often simply default to their standard operating procedures or follow whatever they deem to be "the path of least resistance", which may not be compliant with the parties' preservation requests.
10. The type of joint request as is reflected in Ethicon's Exhibit A to its Reply document, has doubled the administrative processing at the hospitals; the requirement to create, distribute and track payments has doubled; the number of specimens to document and preserve has doubled; and, the amount of space to not only temporarily store the divided specimens, but also all the shipping materials has doubled. Many hospitals' pathology laboratories were already overworked and understaffed trying to stay on top of the basic daily patient pathology requests, but since the new preservation requests (like the letter in Exhibit A to Ethicon's Reply document) and PTOs issued in AMS, the administrative task at almost all hospitals is suffering and has forced additional burden on these departments.

11. Ethicon's Exhibit A to its Reply document (which is a letter from the Tracey Law Firm) contains a paragraph entitled "Instructions for Immediate Preservation of the Specimen(s)" directed to the hospital's pathology department. The letter indicates that the lab will be receiving two sets of instructions to follow regarding the processing of any explant specimens. This is very confusing to the party receiving the letter and would immediately interrupt the preservation process if the pathology department has to wait for two sets of instructions. It has been Steelgate's experience that many of the patients having a TVM procedure have a limited amount of lead time to schedule a procedure. Most are scheduled rather quickly, and if one letter is sent by the plaintiff's counsel and then a second letter is sent from the defense counsel with different preservation instructions, and there is only one specimen available after surgery, this would halt the preservation process in the Operating Room because they would not know how to prepare the preservation. As such, a single preservation process should be determined and implemented.

12. Ethicon's Exhibit A to its Reply document (which is a letter from the Tracey Law Firm) contains a paragraph entitled "Instructions for Division into Equal Specimens" directed to the hospital's pathology department. This is of major concern for a number of reasons. First, as part of a hospital lab's processing of a specimen, they attempt to maintain as much of the specimen intact as possible to preserve the entire specimen. Unfortunately, with mesh explants, there is often very little specimen and thus, per many hospital lab's Standard Operating Procedure (SOP) for basic specimen processing, any remaining specimen is preserved in a paraffin block. Since the mesh specimens are often very small, it is always a challenge for the hospitals to do its best to preserve as much specimen as possible. It has been my company's experience in processing thousands of mesh explants over the course of this litigation, that the labs receiving a request to divide such a small specimen have been resistant to changing their normal operating procedures to comply with a litigation request such as this. If however, there is sufficient specimen to divide AND a hospital is willing to divide a specimen, they then have to find a hospital representative with the time to complete the division. Once the division is finally scheduled, the very specific instructions and division requests are often very difficult for the lab to follow. There is no standard size or consistency of a specimen. The most difficult task is determining how to fairly make the cut to achieve the requested "two equal (or as equal as possible) specimens" and then where to make the cut. It is thus left to the lab representative to identify the specimen; mesh? Tissue? Mucosa? Nodule? Foreign material? Then once the specimen description is determined, the lab representative must refer back to the instructions to make a very specific 'cut', all the while being careful not to have the specimen out of the preservative fluid for too long and throughout the process, having to stop to take photographs, measurements and weight. The original specimen will arrive in one pathology jar and the deliverable will be three pathology jars that must be documented, inventoried, stored and prepared for distribution. Since the documentation, division and distribution of preserved specimens is not part of the lab standard process, the lab must identify and set up and schedule specific staff and allocate work space for the hospital's lab employee necessary to follow the very detailed, requested process. As if it is not already enough of a total inconvenience and disruption to normal daily processing of the lab, the instructions then state that "If in the course of dividing the specimen(s), it

becomes impossible to provide two equal(or nearly equal) halves of the specimen(s), please immediately notify the representatives of the parties listed below. The parties will confer re: access to the specimen(s) and provide further instructions re: same.” In the event that such conference amongst the attorneys then has to occur, the lab technician would have to cease working on the specimen; put it back in preservative; restock the specimen; remove their protective lab gear; and go immediately to a computer so they can email both parties with a status. Then the specimen will sit and wait in a storage area while the two parties discuss the issue and return a decision back to the lab representative. Meanwhile, the lab representative has to document or track the status of the specimen while temporarily being stored in a lab that has limited storage space to begin with. The lab representative just spent a significant portion of their time setting up, preparing the specimen, following the various steps outlined by the parties, and then is unable to complete the tasks until they hear back from the parties. These are the practical considerations for the multitude of hospital labs across the country that we have to deal with. The detailed steps outlined in the preservation letter far exceed any daily tasks the lab representatives complete during any day of usual lab practices and will act as to create confusion and delay in a process that is already clogged and delayed.

13. Ethicon’s Exhibit A also contains “Instructions for Photographing Specimen(s) Before and After Division” directed to the hospital pathology department. This is also of concern for a number of reasons. Most hospitals are not equipped or staffed to take the photographs contemplated by this letter. While the instructions are outlined in the letter as two separate tasks, operationally, the division and documenting of a specimen would be completed simultaneously. Furthermore, the methodology does not stipulate how to measure the specimens. If this stipulation is requesting hospitals to follow its “usual practice” for processing a specimen, it should be pointed out that this is not a “usual practice” for hospital pathology labs to take multiple photographs at specific angles and weigh a specimen throughout a process. As for measuring and weighing a specimen, not all labs have the same scale and/or have the same calibration procedure for the lab equipment and there could be deviations on the weight of the scale producing inconsistent results. The lab may document a specific weight and if a specimen is sent to another location to be analyzed and the weight is recorded, there could be a variation from the weight presented by the hospital lab vs. the expert’s lab measurement. As for additional documentation of photos, if the hospital does have equipment to photograph a specimen, each hospital may have a different media to store the photo; digital, on a cd rom, jump drive, e-file and then there may be additional HIPPA requirements to protect a patient information when specifically labeling the patient photos: will the photos need to be encrypted? What type of electronic security is in place? In measuring the specimen, will a metric ruler be used; if consistency is required, a more detailed procedure would need to be developed and used by every facility, which would be nearly impossible to implement due to a lack of industry standards for equipment and processing procedures. In addition, the many additional steps for preserving, documenting, dividing and distributing specimens, clearly do NOT fall under a hospitals ‘usual practice’ for handling a specimen and creates work back log as well as critical administrative overhead.

I have also reviewed Plaintiffs' proposed pathology preservation PTO (Exhibit B to Plaintiffs' Response document). Based on Steelgate's 14 years of practical experience in retrieving and storing refrigerated, frozen and ambient specimens, that the most successful process is to have a straightforward, consistent, easy process with minimal steps for the lab technicians to follow. The less that has to be interpreted or "figured out" by the lab technician, the less room for human error, even with a request for only documenting, dividing and distributing specimens. Labs are most cooperative if the preservation request does not add any extra steps to the lab technician's already very busy daily requirements. The lab does not want to have to process requests from multiple parties; they want to push a specimen through the lab and move on to the next specimen. If a specimen remains in a lab for any extended length of time, it increases the chance of spoilage or the misplacing a specimen. The more a specimen is handled, the more likely there could be human error and the lab staff does not want to take on any potential exposure for the potential mishandling or misplacing a specimen or not properly following a court ordered requested procedure. Many private labs shy away from assisting in any litigation because of the potential for its employees to have their depositions taken. If the lab staff is pulled into a deposition, they cannot perform their daily tasks and the lab cannot meet its daily commitments and be able to meet client processing deadlines.

14. As proposed by Plaintiffs in their PTO (Exhibit B to Plaintiffs' Response document), the solution is using a central specimen biorepository. The hospitals are not in the business of providing support to law firms for litigation. When asked to provide support, it is with reluctance, delay and often great confusion that they do so. By outsourcing the specimens to a central biorepository, the primary function will be to complete the required tasks for both parties. The centralized specimen biorepository will be able to receive preserved specimens and to fairly manage the documentation, division, storage and distribution of both parties' specimens. The tasks will be a priority and part of the core business. A centralized specimen bio-repository will ensure quality and timeliness and will manage the accessibility and distribution of specimens for all parties. When collecting specimens, the centralized specimen biorepository will be able to simultaneously contact and communicate the status of a specimen to both parties. The communication will be direct to both parties, and they will get the same information, at the same time, with all necessary parties copied on the same email communication. Steelgate has a barcode system and will be able to assure consistent labeling and barcoding of all specimens. The specimens will store in a centralized biorepository which will allow more direct, efficient shipping and tracking of specimens.
15. Centralizing the specimen handling will be more concise and efficient and generate more successful results for staying informed about a specimen and having access to a specimen. Centralizing the specimens to a biorepository will eliminate many of the barriers outlined above that are currently impeding the successful preservation, documentation, division and distribution of a specimen in the mesh MDLs. By removing the preservation, documentation, division and distribution tasks from the hospital/lab and assigning it to a third-party, centralized specimen biorepository, the hospital will be more willing to cooperate when they can return to focusing on the hospital's primary task of caring for the patient.

Kate Grayson
KATE GRAYSON

June 4, 2014
DATED